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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,130	05/14/2001	Keith H.S. Campbell	1966.001001	8898

26111 7590 02/25/2003

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**Application No.  
**09/600,130**Applicant(s)  
**Campbell**Examiner  
**Joseph Weitach**Art Unit  
**1632****-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Dec 2, 2002
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42-82 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 42-82 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

This application is a national stage filing of PCT/GB00/00086, filed January 13, 2000 (amended July 12, 2000 and October 13, 2000), which claims benefit to provisional application 60/130,546 filed April 22, 1999 and claims benefit to foreign application 9900734.6 filed January 13, 1999 in Great Britain.

Upon review of the pending claims, a new restriction requirement is set forth below. Claims 42-82 are pending and currently under examination.

#### ***Election/Restriction***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 42-50, 56-82, drawn to a method of producing an animal embryo comprising passing a diploid nuclear donor through a first recipient oocyte, then into a second oocyte or zygote, the embryo produced by this method, a cell line produced from the embryo and a method of producing an animal from said embryo.

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Group II, claim(s) 42, 51-53, drawn to a method of producing an animal embryo comprising passing a tetraploid nuclear donor through a first recipient oocyte, then into a second oocyte or zygote, the embryo produced by this method, a cell line produced from the embryo and a method of producing an animal from said embryo.

Group III, claim(s) 42, 54, 55, drawn to a method of producing an animal embryo comprising passing a unknown ploidy nuclear donor through a first recipient oocyte, then into a second oocyte or zygote, the embryo produced by this method, a cell line produced from the embryo and a method of producing an animal from said embryo..

The inventions listed as Groups I -III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution over the prior art, or

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product.
- 2) A product and a process of use of said product.
- 3) A product, a special process of manufacture of said product, and a process of use of said product.

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4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention.

The inventions are distinct, each from the other because: The method of producing a reconstituted embryo by passing the nuclear donor through more than one recipient oocyte has been previously disclosed in the art. Strelchenko *et al.* (WO 98/39416) describes the production of multiple nuclear transfer units and methods of culturing in order to produce a cloned animal (see for example schemes in figures 3 and 4 and page 55 Section III). Strelchenko *et al.* teach a method of generating a cloned mammal by serially passaging by nuclear transfer into an oocyte using nuclear transfer technology. Subsequently, the embryo/fetus can be used to generate a cloned mammal. Because the method encompassed by claim 42 for providing an embryo has been previously disclosed in the art, there is not special technical feature which links the various methods instantly claimed.

In addition, upon election of any group an election of species is required. This application contains claims directed to more than one species of the generic invention. These

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species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: claims 59-63 list several different species of animals. Specifically, the claims include specific recitation of cow/bull, pig, sheep, goat, camel, water buffalo, mouse, rat and rabbit. It is noted that Strelchenko *et al.* (WO 98/39416) teaches the use of nuclear transfer for generating a cloned cow (see for example figure 1).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Each of the claims simply reciting practice of the claimed method in an animal are generic to each species. Claim 60 specifically recites cow/bull, pig, sheep, goat, camel, water buffalo, claim 61 specifically recites the rodent species of mouse and rat, and claims 62-63

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specifically recite the lagamorph species of rabbit. Each of claims 60-63 are generic to the specific species recited in the claims.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each species of animal is unique one from the other and in particular for the practice of methodology of nuclear transfer and culturing the resulting embryo into viable animal, each animal requires specific methodology which is not simply adapted to any a second different animal. For example, presently the sheep, goat, cow, cat and mouse have all been cloned using nuclear transfer, however the art teaches that each animal had unique limitations with regard to the nuclear donor cell type, culturing conditions, and oocyte conditioning. Species of animal are unique from each other by definition of an animal species. The art teaches that these differences also extend to the methodology required to practice any general method in each species. Therefore, while each species of animal is considered a species of the large genus of animal, each species is a patentably distinct species because the methods needed to practice would be unique to each animal.

The inventions above are independent and distinct, each from the other. They have acquired a separate status in the art and require independent searches. The search for each of the above invention is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of any one Group would not necessarily anticipate or make obvious any of the other groups.

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For these reasons restriction for examination is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

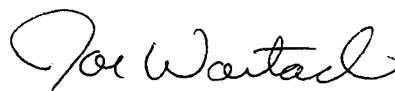
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

  
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